JUL - 5 2000

K001845

510(k) SUMMARY

MALLINCKRODT
GoodKnight 418S

1.0 - Submitter Information

Mallinckrodt Développement France
10, Allée Pelletier Doisy
54601 Villers-lès-Nancy
France

Submitter's Name : Moustafa Anki
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Preparation Date : June 2000

2.0 - Device Name

Proprietary Name : GoodKnight 418S
Common Name : CPAP Machine
Device Classification Name : Noncontinuous Ventilator (73 BZD), per 21 CFR 868.5905

3.0 - Predicate Device Equivalence

We are claiming substantial equivalence to the Mallinckrodt GoodKnight 418A CPAP device, cleared for commercial distribution as per K993584.

4.0 - Device Description

The GoodKnight 418S is designed to deliver Continuous Positive Airway Pressure between 4 and 18 cmH_2O.

The GoodKnight 418S can be powered either by AC mains (100 VAC, 120 VAC or 230 VAC nominal) or by an external 24 VDC battery. The blower motor nominal voltage is 24 VDC, which is obtained directly from the external battery or by rectifying and filtering the nominal mains power. The GoodKnight 418S is double insulated so that grounding is not required.

The GoodKnight 418S is set up for use by the homecare dealer using the Clinician Manual provided. The device is operated according to the instructions contained in the Patient Manual.

The GoodKnight 418S relies on a microprocessor for setting and viewing various control parameters and turning features on and off. The microprocessor is also required for the treatment of various signals from the devices including signals relating to patient cycle detection.

The GoodKnight 418S operates only in Constant mode. The main function of each device is to deliver constant positive airway pressure to the patient at a fixed level prescribed by the practitioner and between 4 and 18 cmH_2O.

The device is also able to detect physiological events (apnea and hypopnea). Data concerning the type of events detected, their frequency and duration etc. is stored in the device data memory and can be accessed by the practitioner through the use of the optional Silverlining™2 software.

Pressure delivery for the GoodKnight 418S is regulated by a pressure sensor which monitors both ambient and output pressure at the patient's mask and provides feedback to the control system.

The following functions are available on the GoodKnight 418S:

- On/Off
- Set Prescription Pressure
- Set Ramp Time
- Set Ramp Starting Pressure
  (available only if Ramp time is not set to 0)
- View Hour Meter
- View Compliance Meter
- View Embedded Software Version

The GoodKnight 418S uses the same pass over humidifier and masks as those approved for use with the GoodKnight 418A. The GoodKnight 418S tubing is equivalent to that of the GoodKnight 418A.

The GoodKnight Control clinical remote is also available for use with the GoodKnight 418S as is for the GoodKnight 418A. The remote is used by the practitioner to configure the devices from a distance via a serial link.

The GoodKnight 418S can also be connected to a computer via an RS232 serial port. The device can be configured from the computer using the Silverlining™2 software that is required for downloading and displaying compliance data stored in the device memory.

The GoodKnight 418S is not for use in life-supporting or life-sustaining situations. The devices and/or their accessories are not intended for sterile use.

The GoodKnight 418S and the air filter are for multiple use. Accessories such as the patient circuit and nasal masks are for single patient use.

The GoodKnight 418S is for use by prescription only and display the appropriate labeling.

The GoodKnight 418S is for use in a hospital and homecare environment.

The GoodKnight 418S does not contain any drugs or biological products as components. However, the device can be used to provide the patient with supplemental oxygen.

The GoodKnight 418S is not part of a kit.

The GoodKnight 418S uses software to set the various device parameters such as the prescription pressure and the ramp starting pressure.

The GoodKnight 418S is electrically operated.

The GoodKnight 418S complies with certain voluntary standards, ~~specifically the draft ARDB Reviewer~~ Guidance for Premarket Notification Submissions (Nov 1993) and IEC 601-1.

5.0 - Intended Use

The intended use of the GoodKnight 418S is to provide Continuous Positive Airway Pressure ~~(C-PAP)~~ between 4 and 18 cmH_2O to spontaneously breathing patients over 30 Kg for the treatment of Obstructive Sleep Apnea in a hospital and homecare environment.

6.0 - Comparison of Technological Characteristics

The GoodKnight 418S and GoodKnight 418A are all C-PAP devices which deliver a constant positive air pressure to the patient at a level prescribed by the practitioner between 4 to 18 cmH_2O ~~(C-PAP mode)~~. However, the GoodKnight 418A (predicate device) can also operate in Automatic mode. In Automatic mode, maximum and minimum pressure ranges are set, for each type of event, above and below the prescribed reference pressure and bet ween 4 to 18 cmH_2O.

The global architecture of the GoodKnight 418A and the GoodKnight 418S is similar. The voltage range for the GoodKnight 418S is 100VAC, 115 VAC nominal, 230 VAC nominal or 24 VDC as for the GoodKnight 418A. The motor voltage of the GoodKnight 418S is 24 VDC as is the GoodKnight 418A device. The GoodKnight 418S and the GoodKnight 418A are all double insulated.

As with the GoodKnight 418A, the GoodKnight 418S uses a microprocessor to set the various controls. In common with the GoodKnight 418A, the GoodKnight 418S have a ramp function which, when activated, progressively attains the set reference pressure wi thin a designated time between 0 to 30 minutes.

The user interfaces of the GoodKnight 418A and the GoodKnight 418S are similar. Both devices use an LCD screen with a four button keypad (one of which is hidden) to access and view various device settings.

The GoodKnight 418A and the GoodKnight 418S have the common feature of compliance and hour meters. Both devices have also a data storage facility for registering information concerning the patient's respiratory cycle for up to 100 sessions. The data memory can be accessed by connecting a PC to the RS232 type interface at the back of the device and through the use of the Silverlining ™2 software.

7.0 - Summary of Performance Testing

1. Functional testing was performed to confirm that the GoodKnight 418S is capable of meeting its stated performance specifications. The device passed all tests.
2. Testing was performed to confirm that the GoodKnight 418S complies with the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" ~~published by the~~ Division of ~~Cardiovascular~~, Respiratory, and Neurological Devices. The device passed all tests.
3. The embedded software was tested in accordance with the May 29, 1998 "Guidance for the Content of Premarket submissions for Software Contained in Medical Devices" published by the Office of Device Evaluation. The device passed all tests.

8.0 - Conclusions

We conclude that the GoodKnight 418S meets the stated performance specifications and criteria outlined in the Reviewers Guidance publications referenced above. We conclude that the device and its accessories will operate safely in its intended environment and will be effective in fulfilling its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2000

Mr. Moustafa Anki
Mallinckrodt Développement France
10, Allée Pelletier Doisy
F-54601 Villers-lès-Nancy Cedex

Re: K001845
GoodKnight 418S
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: June 16, 2000
Received: June 19, 2000

Dear Mr. Anki:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

Device Name :

Mallinckrodt, *GoodKnight 418S*

Intended Use :

The Mallinckrodt GoodKnight 418S is indicated for use in treating obstructive sleep apnea (OSA) in spontaneously breathing patients weighing ~~over 30 kg within~~ a homecare and hospital environment.

Concurence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

510(k) number: K001845

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001845